

**REMARKS**

Claims 5-21 are presently pending in the application.

The Examiner has rejected claim 19 under 35 U.S.C. § 112, second paragraph as being indefinite on the ground that the recitation “wherein the acceleration amounts to a reduction of maturing time of more than 50%” is not clear as to what the maturation time is being measured against. While not necessarily agreeing with the Examiner’s rejection, Applicant has amended claim 19 to specify that the reduction of maturing time is compared to standardized raw sausage without added folic acid or folate. This amendment is supported, for example, in the specification at paragraphs [0026], [0033] and [0041] of the published application US 2006/0105079 A1. Accordingly, no new matter has been added, and entry of the amendment and withdrawal of the rejection under 35 U.S.C. § 112 are respectfully requested.

The Examiner has rejected claims 5-21 under 35 U.S.C. § 103(a) as being unpatentable over Robinson, “Fermented Meat Products” in *Encyclopedia of Food Microbiology* (“Robinson”) in view of Shankman et al, “Vitamin Requirements of Twenty-Three Lactic Acid Bacteria” in *Journal of Biological Chemistry* (“Shankman”) and Snell, “The Nutritional Requirements of Lactic Acid Bacteria and Their Application to Biochemical Research,” *Journal of Bacteriology* (“Snell”). The Examiner contends that Robinson discloses a method of making a semi-dry sausage comprising steps of providing minced meat, mixing the minced meat with various additives including spices, and fermenting the sausage for 9-23 days at a relative humidity of 58-95% and a temperature of 12-30° C. The Examiner also notes that Robinson discloses that the desired sensory characteristics of the fermented sausage products are associated with the dominance of lactic acid bacteria, which contribute to the inhibition of spoilage and pathogenic bacteria, and that lactic acid bacteria are commonly used in starter cultures.

The Examiner acknowledges that Robinson does not explicitly disclose adding from about 4 mg. to about 25 mg. per kilogram of meat a material selected from the group consisting of folic acid and folate. However, the Examiner agrees that Shankman teaches that folic acid is known to be stimulatory or essential for growth of lactic acid bacteria and that Snell teaches that

lactic acid bacteria require complex media for rapid growth including folic acid, which is a vitamin for lactic acid bacteria.

The Examiner concludes that Robinson, Shankman and Snell are combinable because they are concerned with the same field of endeavor, namely lactic acid bacteria, and that it would have been obvious to one skilled in the art to have added a folic acid-containing media as taught by Shankman and Snell to the raw sausage meat of Robinson for the purpose of encouraging rapid growth of desired lactic acid bacteria during maturation. The Examiner concedes that Shankman and Snell provide little guidance as to how much of each media component, including folic acid, is required for rapid growth or maturation, but given that folic acid is a known stimulator or essential for growth component of lactic acid bacteria, one skilled in the art would have found it obvious to adjust, by routine processing, the amount of folic acid added to stimulate growth and fermentation of the lactic acid bacteria. The Examiner goes on to argue why all of the dependent claims would have been obvious from Robinson modified by Shankman and Snell.

This rejection is respectfully but strenuously traversed for the reasons set forth in detail below.

The Examiner's rejection is clearly an improper hindsight rejection, which appears to be based upon Applicant's proposed mechanism in paragraph [0023] of the present application that the stimulation of the natural maturing processes by adding folic acid and/or folate may be explained by the rapid increase of the number of microorganisms generated by micro-cocci or lacto-bacteria and the like, which lead to generating lactic acid and specific fermentation products faster and better than at the normal production of raw sausage. Such use of Applicant's own disclosure to attempt to reconstruct and relate the prior art is totally improper. In any event, regardless of the effect of lacto-bacteria or lactic acid, none of the prior art teaches or suggests the acceleration of the microbiological maturing process by adding folic acid or folate as presently claimed.

The Examiner has attempted to justify the combination of Robinson, Shankman and Snell on the ground that they are concerned with the same field of endeavor, namely lactic acid

bacteria. While it is true that Snell and Shankman are directed to lactic acid bacteria and their nutritional requirements for growth, Robinson is directed to the fermentation of meat products and only mentions lactic acid bacteria as desirable flora being present in fermented meat. Moreover, Robinson was published over sixty years later than the Snell and Shankman publications, making it highly unlikely that one of ordinary skill in the art would have considered combining these three references to try to achieve the present invention.

Turning to the specific disclosures of the three references, neither Shankman nor Snell describes the specific lactic acid bacteria, which according to Robinson are used in starter cultures. In Table III of Shankman a number of different lactic acid bacteria are described from among which the Examiner has specifically referred to *L. delbrückii* LD5 and *L. casei*. These bacteria strains appear to be stimulated by the addition of folic acid. However, neither *L. delbrückii* nor *L. casei* according to Robinson are present in regular starter cultures. Moreover, folic acid is not essential for most of the other lactic acid bacteria, whereas e.g. biotin and thiamine stimulate the growth of *L. gayonii* and *L. mesenteroides*, riboflavin stimulates the growth of *L. mesenteroides* and pyridoxine stimulates the growth of *L. brassicae*, *L. arabinosus* and the two *L. mesenteroides* strains. Therefore, it is by no means obvious that the skilled practitioner would have added folic acid to the starter cultures according to Robinson to stimulate the growth of lactic acid bacteria.

Similarly, in Table III of Snell (page 379) folic acid is described to be stimulating to the growth of *L. casei* and *L. delbrückii* only, whereas e.g. *L. arabinosus* or *leuconostoc mesenteroides* are not stimulated. Also in this table a number of alternative stimulants are described which have an impact on all mentioned lactic acid bacteria such as pantotenic acid, nicotinic acid and biotin. As a result, the combination of Robinson on the one hand and Shankman or Snell on the other hand does not in any way suggest the addition of folic acid during the fermentation process.

The conclusion that an improved growth of the lactic acid bacteria accelerates the maturation of a sausage can also not be derived from Robinson. In Robinson it is only pointed out, that the desired organoleptic properties of the products are associated with the

dominance of these bacteria and that these bacteria are usually present in excess at the end of the maturation period, which does not justify such a conclusion.

It is further pointed out that, according to Shankman, the addition of folic acid is not only essential for the growth of *L. casei* and *L. delbrückii*, but also for the potentially pathogenic bacterium *streptococcus faecalis*. These bacteria are obviously not desired in food products, so that the addition of folic acid would not only have positive consequences, but negative consequences as well. Even if the skilled practitioner may have combined the references, there is no basis for reasonably expecting that the combination would have resulted in the claimed method of accelerating the microbiological maturing process in making raw sausage.

Further, none of the references suggests the addition of the quantity of about 4 mg to about 25 mg of folic acid and/or folate per kilogram of raw sausage, as presently claimed. In fact, Snell specifies only 5 micrograms of folic acid per liter of growth medium for lactic acid bacteria (page 378, Table 2) as a vitamin supplement for lactic acid bacteria growth. The Examiner argues that given folic acid as a known stimulator or essential for growth component of lactic acid bacteria, one of ordinary skill in the art would have found it obvious to adjust by routine processing the amount of folic acid added to stimulate growth and fermentation of the lactic acid bacteria. Assuming this is so, one skilled in the art would have used only 5 micrograms, not about 4-25 milligrams of folic acid. In any event, the presently claimed invention is not directed to stimulating the growth and fermentation of lactic acid bacteria, but rather the acceleration of the microbiological maturing process in making raw sausage.

In sum, none of the three prior art references relied upon by the Examiner in this rejection teaches or suggests accelerating the microbiological maturing process in making raw sausage. Even if properly combinable, the three references at best teach enhancing the growth of lactic acid bacteria. Moreover, none of the references teaches or suggests the addition of an amount of about 4 to 25 milligrams folic acid and/or folate per kilogram of raw sausage meat. Accordingly, the rejection is improper and reconsideration and withdrawal are respectfully requested.

The Examiner has also rejected claims 5-21 under 35 U.S.C. § 103(a) as being unpatentable over Robinson in view of Henry et al, "*Nutrition Handbook for Food Processors-*

Section 8.6: Nutritional Enhancement vs. Food Fortification” (“Henry”) and Rader and further evidenced by Kerry et al. Robinson, Rader and Kerry were previously relied upon by the Examiner in rejecting the claims in the previous Office Action.

The Examiner relies upon Robinson, Rader and Kerry for essentially the same disclosures and reasons as the previous Office Action. The Examiner concedes that Robinson does not explicitly disclose adding from about 4 mg to about 25 mg per kilogram of meat a material selected from the group consisting of folic acid and folate and that Rader teaches adding folic acid as a nutritional additive to cereal grain at a level of only 140 µg folic acid per 100 grams of cereal-grain product. However, the Examiner contends that Henry teaches that folates have the effect of reducing levels of plasma homocysteine, which are a risk for cardiovascular disease and stroke, and further that Henry teaches increasing the dietary levels of folate from the current average of 200 µg per day to 600 µg per day to achieve the idea level of plasma homocysteine.

Based upon this teaching, the Examiner calculates that one serving of 100 grams of sausage, as presently claimed, would comprise 400 to 2500 µg folic acid or folate, and concludes that this would fall within the daily intake of folic acid or folate recommended by Henry. Finally, the Examiner concludes that this combination of references with Robinson discloses a method substantially similar to that presently claimed, so that it follows that the microbiological maturing process time would be reduced. This rejection is also respectfully but strenuously traversed for the reasons set forth in detail below.

As an initial matter, the Examiner’s calculations in the first full paragraph of page 9 are totally contrived and inaccurate. Rader teaches adding folic acid to cereal at a level of 140 µg folic acid per 100 grams of cereal-grain product. In contrast, Henry teaches dietary levels of folate should be 600 µg per day. Clearly, no average person eats only 100 grams of food per day, and Henry does not in any way suggest that any particular food, much less sausage meat, be supplemented at a level of 600 µg per 100 gram of food product. Given that the average person probably consumes somewhere in the range of 1 to 2 kilograms of food per day, Henry’s proposed dietary levels of folate would be about 30-60 µg per 100 grams of food, i.e., lower than the level taught by Rader for cereal-grain products.

Therefore, Henry adds nothing at all to the Examiner's previous combination of Robinson, Rader and Kerry, which has apparently been withdrawn, since it was not repeated in the present Office Action. Further, like Rader and Kerry, Henry has nothing to do with a method for accelerating the microbiological maturing of sausage meat, but is solely directed to fortifying dietary levels. Moreover, none of these references recognizes that folic acid or folate added to a raw sausage meat mixture would decrease during the maturing process, so that the amounts recommended by these references would not be achieved in the final product if added to raw sausage meat before aging. That is, even if the combination of Robinson, Rader, Kerry and Henry were proper, they would at best suggest adding folic acid to food products in a final step, not at the beginning of the process, so that the desired levels would be achieved in the final food product.

Finally, as pointed out in connection with the first rejection, the newly cited reference of Snell not only describes that the growth of lactic acid bacteria can be stimulated by the addition of folic acid, but also that the growth of pathogenic bacterium streptococcus faecalis is stimulated. Therefore, it would have been highly unlikely that the person skilled in the art, in view of the danger of promoting the growth of potentially pathogenic bacteria, would have added folic acid during the production process of raw sausage meat. If anything, the person skilled in the art would have circumvented this danger by adding folic acid only after the sausage is fully matured. However, that is not the presently claimed invention, which allows the raw sausage meat to mature microbiologically after addition of the folic acid and/or folate.

Accordingly, for the above reasons, as well as the reasons set forth in response to the previous Office Action, this rejection is improper and should be withdrawn. Reconsideration and withdrawal of the rejections are respectfully requested.

In view of the above Remarks, the present claims patentably distinguish over the prior art of record. Reconsideration and an early Notice of Allowance are respectfully requested.

Respectfully submitted,

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WWS/rdb

Enclosure: Petition for Extension of Time (two-months)